

## **REMARKS**

Claims 1, 5-8, 10-16, 18 and 19 are pending in this application. Claims 2-4, 9, 17 and 20 have been canceled.

New Claims 21-23 have been added to further clarify and define the invention disclosed in the present application. These claims find support in the specification of the application as originally filed and, thus, no new matter has been added by the introduction of the claims. Applicant respectfully requests examination and allowance of Claims 21-23.

The Examiner has rejected claims Claims 1, 5-8, 10-16, 18 and 19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,938,969 to Schinitzky et al. (hereafter "Schinitzky"), in view of U.S. Patent No. 5,804,594 to Murad (hereafter "Murad"), in further view of U.S. Patent No. 5,902,591 to Herstein (hereafter "Herstein"), and in further view of U.S. Patent No. 2,517,276 to Bassford et al. (hereafter "Bassford").

The Examiner has also rejected claims Claims 1, 5-8, 10-16, 18 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Schinitzky, in view of Murad, in further view of U.S. Patent No. 5,140,043 to Darr et. al. (hereafter "Darr"), in further view of Bassford, and in further view of U.S. Patent No. 5,700,451 to Yue et al. (hereafter "Yue").

For at least the reasons set forth below, withdrawal of all outstanding rejections is respectfully requested.

### **Prior Art Rejections**

#### **Section 103(a) rejections:**

The Examiner has rejected claims Claims 1, 5-8, 10-16, 18 and 19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,938,969 to Schinitzky et al.

(hereafter "Schinitsky"), in view of U.S. Patent No. 5,804,594 to Murad (hereafter "Murad"), in further view of U.S. Patent No. 5,902,591 to Herstein (hereafter "Herstein"), and in further view of U.S. Patent No. 2,517,276 to Bassford et al. (hereafter "Bassford").

The Examiner has also rejected claims Claims 1, 5-8, 10-16, 18 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Schinitsky, in view of Murad, in further view of U.S. Patent No. 5,140,043 to Darr et. al. (hereafter "Darr"), in further view of Bassford, and in further view of U.S. Patent No. 5,700,451 to Yue et al. (hereafter "Yue").

Applicant respectfully traverses all of the above rejections.

Applicant respectfully submits that the Examiner has suggested an improper (and highly improbable) hindsight combination of the cited references that – even if one of ordinary skill in the art could find motivation to make such highly speculative and selective modifications – would not successfully render all of the required elements of the pending claims.

Applicant notes that, in several instances, the Examiner provides – as motivation for such a highly speculative and selective combination of *six* disparate prior art references – “the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.”

Applicant respectfully notes, and respectfully reminds the Examiner, that such is *not* the proper standard for an obviousness rejection. In addition to finding every element of the invention in combined prior art references, one of *ordinary* skill in the art would – *prospectively* – have to find motivation or suggestion to combine the references in the manner suggested. In this case – in order to realize the prior art combinations suggested by the Examiner – one of

ordinary skill in the art would prospectively have to find motivation or suggestion to combine highly selective elements from, and disregard significant portions of, *six* disparate prior art references.

In light of the following remarks, addressing each claim sequentially, Applicants respectfully request reconsideration and allowance of all claims pending in this application.

**Claim 1:**

Applicant respectfully traverses the Examiner's characterization of the disclosures and suggestions of the Schinitzky, Murad, Herstein, Bassford, Darr and Yue references.

Claim 1 of the present application requires a composition comprising at least 10% (w/v) ascorbic acid; an aminosugar; and water; wherein the composition has a pH of 3.5 to 4.1.

Applicant finds that Schinitzky is directed to a composition for reducing the depth or intensity of fine wrinkles in skin; and discloses a combination comprising ascorbic acid, tyrosine and a non-toxic zinc salt. **Schinitzky teaches zinc sulfate as a necessary ingredient** in its formulation. (Col. 2, lines 54-57).

Schinitzky discloses a composition with, or without, only tyrosine – an amino acid. Applicant finds no disclosure within Schinitzky of an amino sugar. A single entry within Table 1 (Col. 3) refers to Glycerine – a sugar alcohol, not an amino sugar.

Applicant also finds that **Schinitzky contains no teaching or suggestion of pH values or their significance to the invention.**

Thus, in order to achieve the prior art combination of references rendering Claim 1 obvious, as suggested by the Examiner, one of ordinary skill in the art having only Schinitzky

before him would have to: 1) read and fully understand Schinitzky; 2) spontaneously decide that the inventive composition in Schinitzky was somehow deficient or in need of modification; 3) spontaneously disregard Schinitzky's teachings of ascorbic acid percentages of 2% to 10%; 4) spontaneously assume, without prompting, that pH values of a composition should be of importance; 5) spontaneously disregard Schinitzky's teaching of (and primary focus on) the **necessity** of zinc sulfate in the composition; 6) spontaneously assume that the composition needed an amino sugar; and 7) seek out and find the Murad reference.

Applicant finds that Murad is directed to a pharmaceutical composition for the prevention of wrinkles and improvement of skin elasticity and softness. Murad discloses that **oral administration** of its composition is **preferred**, and presents its disclosure in reference to orally administered examples. (Col. 8, lines 43-46; Cols. 9-15).

Murad discloses a composition comprising a sugar compound (N-acetylglucosamine compound or salt or ester thereof, in ~ 5% – 50% w/v); a primary antioxidant component (an ascorbic acid component or salt or ester thereof, in ~ 5% – 50% w/v); an amino acid component (proline, lysine, cysteine, or methionine, in ~ 8% – 60% w/v); and a transition metal component (zinc, manganese or copper, or mixtures thereof, in ~ 0.5% – 15% w/v). Murad discloses embodiments that further comprise a catechin-based preparation; a glucosamine or a pharmaceutically acceptable salt or ester thereof; and a chondroitin or a pharmaceutically acceptable salt or ester thereof. Murad discloses still other embodiments that even further comprise a vitamin E source; a cysteine source; a vitamin B<sub>3</sub> source; a methionine source; a vitamin A source; and other various elements.

Applicant finds that Murad discloses the necessity of an amino acid (Col. 5; lines 14-18; Col. 6, lines 9-11), and includes such in all disclosed embodiments. Similarly, Murad discloses the necessity of a transition metal component (Col. 5; lines 22-24; Col. 6, lines 33-36), and includes such in all disclosed embodiments.

Murad discloses that **oral administration** of its composition **is preferred**. (Col. 8, lines 43-46; Cols. 9-15).

Applicant also finds that **Murad contains no teaching or suggestion of pH values or their significance to the invention.**

Thus, in order to achieve the prior art combination of references rendering Claim 1 obvious, as suggested by the Examiner, one of ordinary skill in the art would have to: 1) read and fully understand Schinitsky; 2) spontaneously decide that the inventive composition in Schinitsky was somehow deficient or in need of modification; 3) spontaneously disregard Schinitsky's teachings of ascorbic acid percentages of 2% to 10%; 4) spontaneously assume, without prompting, that pH values of a composition should be of importance; 5) spontaneously disregard Schinitsky's teaching of (and primary focus on) the **necessity** of zinc sulfate in the composition; 6) spontaneously assume that the composition needed an amino sugar; 7) seek out and find the Murad reference; 8) read and fully understand Murad; 9) disregard Murad's substantial teaching and suggestion of the preferability of **oral composition and administration**, selectively culling only a few elements from Murad to apply to Schinitsky's **topical** formulation; 10) spontaneously disregard Murad's teachings of ascorbic acid percentages of 5% to 10%; 11) spontaneously disregard Murad's teachings of the necessity of amino acids; 12) selectively disregard Murad's teaching of transition metals other than zinc sulfate; 13) spontaneously

assume, despite no teaching or suggestion by either Schinitzky or Murad, that pH values of a composition should be of importance; 14) selectively disregard all of Murad's teachings of the usefulness or desirability of other ingredients; 15) successfully modify Schinitzky's composition to include glucosamine or another amino sugar; 16) spontaneously assume that the resulting composition was still somehow incomplete or deficient; and 17) seek out and find the Herstein reference.

Applicant finds that Herstein is directed to a stable topical emulsion for cosmetic/pharmaceutical purposes, made from a two component system of a powdered ascorbic acid phase and a liquid phase. The liquid phase contains an effective amount of an organoclay material to stabilize the emulsion.

Herstein discloses a topical emulsion having **ascorbic acid** from about 0.1% - 20% (w/v); with **preferred embodiments comprising 2% - 10%, and most-preferred embodiments comprising 4% - 8%.** (Col. 2, lines 53-60).

Applicant can find **no disclosure with Herstein of an amino sugar.**

Thus, in order to achieve the prior art combination of references rendering Claim 1 obvious, as suggested by the Examiner, one of ordinary skill in the art would have to: 1) read and fully understand Schinitzky; 2) spontaneously decide that the inventive composition in Schinitzky was somehow deficient or in need of modification; 3) spontaneously disregard Schinitzky's teachings of ascorbic acid percentages of 2% to 10%; 4) spontaneously assume, without prompting, that pH values of a composition should be of importance; 5) spontaneously disregard Schinitzky's teaching of (and primary focus on) the **necessity** of zinc sulfate in the composition; 6) spontaneously assume that the composition needed an amino sugar; 7) seek out

and find the Murad reference; 8) read and fully understand Murad; 9) disregard Murad's substantial teaching and suggestion of the preferability of *oral composition and administration*, selectively culling only a few elements from Murad to apply to Schinitsky's *topical* formulation; 10) spontaneously disregard Murad's teachings of ascorbic acid percentages of 5% to 10%; 11) spontaneously disregard Murad's teachings of the necessity of amino acids; 12) selectively disregard Murad's teaching of transition metals other than zinc sulfate; 13) spontaneously assume, despite no teaching or suggestion by either Schinitsky or Murad, that pH values of a composition should be of importance; 14) selectively disregard all of Murad's teachings of the usefulness or desirability of other ingredients; 15) successfully modify Schinitsky's composition to include glucosamine or another amino sugar; 16) spontaneously assume that the resulting composition was still somehow incomplete or deficient; 17) seek out and find the Herstein reference; 18) read and fully understand Herstein; 19) spontaneously disregard Herstein's teachings of ascorbic acid percentages of 0.1% to 10%; 20) spontaneously disregard Herstein's teachings of **preferred ascorbic acid percentages of 2% - 10%, and most-preferred of 4% - 8%**; 21) selectively disregard all of Herstein's teachings of the usefulness or desirability of other ingredients; 22) selectively cull from Herstein only the suggestion of the usefulness of a pH value of 3.5 to 4.1; and 23) successfully modify the Schinitsky/Murad combination to have a final pH value of 3.5 to 4.1.

Applicant notes that the teachings and suggestions of Bassford, Darr and Yue are addressed in later reference, where applicable to the other claims of the present application. Applicant respectfully submits that, in light of the remarks made thus far, and the general

similarity of the references, specific review of those references in relation to Claim 1 would be redundant and unnecessary.

Applicant does generally note, however, that the disclosure in Darr that transition metal ions catalyze oxidative degradation (Col. 2, line 4) would appear to teach away from combination with Murad, which discloses *the necessity of a transition metal component* (Col. 5; lines 22-24; Col. 6, lines 33-36).

Applicant respectfully submits that one of ordinary skill in the art, at the time the invention of the present application was made, would not be prompted or motivated by the cited references to embark on such a highly speculative, selective, and unnavigable combination, without the assistance of the present application's disclosure.

Absent an improper hindsight reconstruction, the required elements of Claim 1 are not *prospectively* taught or suggested by the cited references. Moreover, the Examiner has already admitted that "the prior art does not expressly disclose the combination of at least 10% of ascorbic acid, amino-sugar, water and pH of 3.5 to 4.1."

Applicant respectfully submits that Claim 1 overcomes the obviousness rejections over the cited references. Claim 1 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 1.

**Claims 2-4:**

Claims 2-4 have been canceled.



**Claim 5:**

Claim 5 depends from allowable Claim 1 and provides, at least, claim differentiation. Applicant respectfully submits that Claim 5 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 5.

**Claim 6:**

Claim 6 depends from allowable Claim 1 and provides further limitations differentiating over the cited references. Applicant can find no disclosure or suggestion of monodehydroascorbic acid in the cited references. Applicant respectfully submits that Claim 6 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 6.

**Claim 7:**

Claim 7 depends from allowable Claim 1 and provides, at least, claim differentiation. Applicant respectfully submits that Claim 7 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 7.

**Claim 8:**

Claim 8 depends from allowable Claim 1 and provides further limitations differentiating over the cited references. Applicant can find no disclosure or suggestion of topical treatment of

inflammatory skin conditions. All of the cited references appear to be directed to treatment of wrinkles, or to sunscreen or cosmetic applications.

Applicant respectfully submits that Claim 8 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 8.

**Claim 9:**

Claim 9 has been canceled.

**Claim 10:**

Claim 10 depends from allowable Claim 5 and provides further limitations differentiating over the cited references.

Applicant respectfully notes that Murad specifically teaches away from glucosamine in the amount of approximately 20% (w/v). (Col. 7, lines 30-44).

Applicant respectfully submits that Claim 10 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 10.

**Claim 11:**

Claim 11 depends from allowable Claim 1 and provides, at least, claim differentiation. Applicant respectfully submits that Claim 11 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 11.

**Claim 12:**

Claim 12 depends from allowable Claim 8 and provides further limitations differentiating over the cited references.

Applicant respectfully notes that none of the cited references disclose or suggest the inflammatory skin conditions required by Claim 12.

Applicant respectfully submits that Claim 12 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 12.

**Claims 13-16:**

Claims 13-16 depend from allowable Claim 1 and provide, at least, claim differentiation. Applicant respectfully submits that Claims 13-16 stand in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claims 13-16.

**Claim 17:**

Claim 17 has been canceled.

**Claim 18**

Applicant respectfully traverses the Examiner's characterization of the disclosures and suggestions of the Schinitzky, Murad, Herstein, Bassford, Darr and Yue references.

Claim 18 of the present application requires a method of treating rosacea or other inflammatory skin affliction, comprising topic application to the afflicted skin of a composition

comprising at least 5.0% (w/v) pre-treated ascorbic acid; at least 10% (w/v) glucosamine or other anti-inflammatory aminosugar; and water, wherein the composition has a pH of 3.5 to 4.1.

Applicant notes that the Examiner has rejected Claim 18 on the same grounds as Claim 1. Applicant hereby incorporates the remarks made above in relation to Claim 1.

Applicant further notes that no disclosure or suggestion of topical treatment of inflammatory skin conditions is apparent in the cited references. All of the cited references appear to be directed to treatment of wrinkles, or to sunscreen or cosmetic applications.

Applicant respectfully submits that Claim 18 overcomes the obviousness rejections over the cited references. Claim 18 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 18.

**Claim 19:**

Claim 19 depends from allowable Claim 13 and provides, at least, claim differentiation. Applicant respectfully submits that Claim 19 stands in allowable form.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of Claim 19.

**Claim 20:**

Claim 20 has been canceled.

**New Claims:**

**Claims 21-23:**

Claims 21-23 depend from allowable independent claims, and provide further limitations distinguishing over the cited references. Applicant respectfully submits that Claims 21-23 stand in allowable form.

**Conclusion**

Applicant respectfully submits that – in light of this response addressing the Examiner's rejections – the instant application, including Claims 1, 5-8, 10-16, 18, 19, and 21-23, is in condition for allowance.

Applicant respectfully requests reconsideration and withdrawal of the rejections, and allowance of all pending claims.

Respectfully submitted,

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